

WHAT IS CLAIMED IS:

1. A composition comprising a recombinant adenovirus vector and a concentration of human serum albumin (HSA) effective to stabilize the adenovirus vector at a temperature above the freezing point of water or to enhance a titer of the adenovirus vector compared to a titer in the absence of HSA, or both, in an aqueous buffer.
2. The composition of claim 1, wherein the concentration of HSA is from about 0.01% to about 25% (w/v).
3. The composition of claim 2, wherein the concentration of HSA is from about 0.1% to about 15%.
4. The composition of claim 3, wherein the concentration of HSA is from about 1% to about 10%.
5. The composition of claim 4, wherein the concentration of HSA is about 5%.
6. The composition of claim 1, wherein the pH is greater than or equal to 5.0 and less than or equal to 9.0.
7. The composition of claim 6, wherein the pH is greater than 7.5.
8. The composition of claim 7, wherein the pH is greater than 8.0.
9. The composition of claim 8, wherein the pH is 8.2.
10. The composition of claim 8, wherein the pH is 8.4.
11. The composition of claim 4, wherein the pH is greater than 8.0.
12. The composition of claim 5, wherein the pH is 8.2.
13. The composition of claim 5, wherein the pH is 8.4.
14. The composition of claim 1, wherein the buffer is a Tris-HCl buffer.
15. The composition of claim 11, wherein the buffer is a Tris-HCl buffer.
16. The composition of claim 12, wherein the buffer is a Tris-HCl buffer.

17. The composition of claim 13, wherein the buffer is a Tris-HCl buffer.
18. The composition of claim 1, further comprising about 5% sucrose, about 2.0 mM  $\text{MgCl}_2$  and about 150 mM NaCl.
19. The composition of claim 15, further comprising about 5% sucrose, about 2.0 mM  $\text{MgCl}_2$  and about 150 mM NaCl.
20. The composition of claim 16, further comprising about 5% sucrose, about 2.0 mM  $\text{MgCl}_2$  and 150 mM NaCl.
21. The composition of claim 17, further comprising about 5% sucrose, about 2.0 mM  $\text{MgCl}_2$  and 150 mM NaCl.
22. The composition of claim 1, wherein the recombinant adenovirus expresses a heterologous protein.
23. The composition of claim 22, wherein the heterologous protein is p53.
24. The composition of claim 22, wherein the heterologous protein is HSV-TK.
25. A method for preparing a stabilized recombinant adenovirus formulation comprising suspending a recombinant adenovirus in an aqueous buffer comprising a concentration of human serum albumin (HSA) effective to stabilize the adenovirus vector at a temperature above the freezing point of water, or enhance a titer of the adenovirus vector compared to a titer in the absence of HSA.
26. The method according to claim 25, wherein the temperature is greater than or equal to 4°C and less than 37°C.
27. The method according to claim 25, wherein the temperature is greater than or equal to 20°C.
28. The method according to claim 26, wherein the concentration of HSA is 5%.
29. The method according to claim 26, wherein the pH of the admixture is greater than 8.0.
30. The method according to claim 26, wherein the pH of the admixture is 8.2.
31. The method according to claim 26, wherein the pH of the admixture is 8.4.
32. A method for stabilizing an adenovirus vector at about 20°C, which comprises preparing an

admixture of the adenovirus vector in an aqueous composition of Dulbecco's phosphate buffered saline, from about 5% to 15% glycerol, from about 0.25 to 2.0 mM  $\text{CaCl}_2$ , and from about 0.1 to 1.0 mM  $\text{MgCl}_2$ .

33. The method according to claim 32, wherein the concentration of glycerol is about 10%, the concentration of  $\text{CaCl}_2$  is about 1.0 mM, and the concentration of  $\text{MgCl}_2$  is about 0.5 mM.

09675-18515